

§ 121.2

microorganism or infectious substance, capable of causing:

(1) Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;

(2) Deterioration of food, water, equipment, supplies, or material of any kind; or

(3) Deleterious alteration of the environment.

Facility. Any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site that may transfer or receive through any means a biological agent or toxin subject to this part.

Overlap agent or toxin. A microorganism (including a virus, bacterium, fungus, rickettsia) or toxin that poses a risk to both human and animal health and that is listed in §121.2(a). The term also includes:

(1) Genetically modified microorganisms or genetic elements from organisms listed in §121.2(a), shown to produce or encode for a factor associated with a disease; and

(2) Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in §121.2(a), or their toxic subunits.

Person. Any individual, firm, corporation, company, society, or association; any Federal, State, or local governmental entity; or any organized group of any of the foregoing.

Responsible facility official. An official authorized to transfer and receive biological agents or toxins, including overlap agents and toxins, covered by this part on behalf of a facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives a biological agent or toxin at the facility.

Toxin. The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes:

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(1) Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or

(2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.

[67 FR 52388, Aug. 12, 2002, as amended at 67 FR 60520, Sept. 26, 2002]

§ 121.2 List of biological agents and toxins.

The biological agents and toxins listed in this section have been determined to have the potential to pose a severe threat to both human and animal health, to animal health, or to the production and marketability of animal products. Unless exempted under paragraph (c) of this section, any person who possesses any listed agent or toxin or, in the case of a listed disease, the causative agent of that disease, must notify the Animal and Plant Health Inspection Service of that possession in accordance with §121.3.

(a) *Overlap agents and toxins.*

(1) *Bacillus anthracis.*

(2) *Brucella abortus*, *B. melitensis*, *B. suis*.

(3) *Burkholderia (Pseudomonas) mallei.*

(4) *Burkholderia (Pseudomonas) pseudomallei.*

(5) *Clostridium botulinum.*

(6) *Coccidioides immitis.*

(7) *Coxiella burnetii.*

(8) Eastern equine encephalitis virus.

(9) Equine morbillivirus (Hendra virus).

(10) *Francisella tularensis.*

(11) Rift Valley fever virus.

(12) Venezuelan equine encephalitis virus.

(13) Aflatoxins.

(14) Botulinum toxins.

(15) *Clostridium perfringens* epsilon toxin.

(16) Shigatoxin.

(17) Staphylococcal enterotoxins.

(18) T-2 toxin.

(b) *Animal agents and toxins.*

African horsesickness virus

African swine fever

Akabane virus

Avian influenza (highly pathogenic)

Bluetongue virus (exotic)

Bovine spongiform encephalopathy agent

Camel pox virus

Classical swine fever

Cowdria ruminantium (heartwater)
 Foot-and-mouth disease virus
 Goat pox virus
 Japanese encephalitis virus
 Lumpy skin disease virus
 Malignant catarrhal fever
 Menangle virus
Mycoplasma capricolum /*M. F38*/*M. mycoides capri* (contagious caprine pleuropneumonia)
Mycoplasma mycoides mycoides (contagious bovine pleuropneumonia)
 Newcastle disease virus (exotic)
 Nipah virus
 Peste des petits ruminants
 Rinderpest virus
 Sheep pox
 Swine vesicular disease virus
 Vesicular stomatitis (exotic)

(c) *Exemptions.* Persons possessing products that are, bear, or contain overlap agents or toxins listed in paragraph (a) of this section will be exempt from the notification requirements of § 121.3 if the products have been cleared, approved, licensed, or registered pursuant to:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*);

(2) Section 351 of Public Health Service Act (42 U.S.C. 262);

(3) The Act commonly known as the Virus-Serum-Toxin Act (the eighth paragraph under the heading “Bureau of Animal Industry” in the Act of March 4, 1913; 21 U.S.C. 151–159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 *et seq.*).

§ 121.3 Notification requirements and procedures.

(a) Any person or facility that possesses any biological agent or toxin listed in § 121.2(b) must notify the Animal and Plant Health Inspection Service (APHIS) of such possession by October 11, 2002. Any person or facility that possesses any biological agent or toxin listed in § 121.2(a) that is not exempt under § 121.2(c) must notify APHIS of such possession by September 10, 2002. Notice must be provided using the form “Notification of Possession of Select Agents or High Consequence Livestock Pathogens and Toxins.” A machine-readable version of the form may be obtained by calling (866) 567-4232. An alternate version of the form is available on the Internet at <http://www.aphis.usda.gov/vs/ncie>.

(b) Each facility should designate a responsible facility official to complete the form, and a single form that reflects all listed agents and toxins possessed by all persons within the facility should be submitted for each facility. The responsible facility official for each facility should consult with others in the facility (*e.g.*, principal investigators) in order to obtain the information necessary to complete the notification form. The responsible facility official must review and sign the notification form and will be the individual contacted by APHIS if any questions arise concerning the facility’s response.

(c) Completed forms must be mailed to: Analytical Sciences, Inc., Attn: FSO P.O. Box 341809, Bethesda, MD 20827-1809.

(d) Assistance in completing the form available on the Internet may be requested by calling (301) 734-3222. Assistance in completing the machine-readable form may be obtained by calling (866) 567-4232.

(Approved by the Office of Management and Budget under control number 0579-0201)

EFFECTIVE DATE NOTE: At 67 FR 76931, Dec. 13, 2002, part 121 was revised, effective Feb. 11, 2003. For the convenience of the user, the revised text is set forth as follows:

PART 121—POSSESSION, USE, AND TRANSFER OF BIOLOGICAL AGENTS AND TOXINS

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- 121.1 Definitions.
- 121.2 Purpose and scope.
- 121.3 List of biological agents and toxins.
- 121.4 Exemptions for overlap agents or toxins.
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- 121.6 Registration; who must register.
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- 121.10 Responsibilities of the responsible official.
- 121.11 Restricting access to biological agents and toxins.
- 121.12 Biosafety and security plan.
- 121.13 Training.
- 121.14 Transfer of biological agents and toxins.
- 121.15 Records.
- 121.16 Inspections.